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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of a Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in PCT Patent Application No. PCT/US2005/12289, U.S. Patent No. 7,901,881, U.S. Patent Application No. 13/024,845 and foreign equivalents thereof entitled “Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions” (HHS Ref. No. E-124-2004/0,1,2) and PCT Patent Application No. PCT/US2008/010139 and U.S. Patent Application No. 12/675,209 entitled “Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions” (HHS Ref. No. E-326-2007/0) to Veracyte, Inc., which is located in San Francisco, California. The patent rights in these inventions have been assigned to the United States of America.

Other than license applications submitted as objections to this Notice of Intent to Grant an Exclusive License, no further license applications will be considered for the exclusive field of use set forth below if Veracyte, Inc. is granted an exclusive license pursuant to this Notice of Intent to Grant an Exclusive License. The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the diagnosis and prognosis of thyroid cancer.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [Insert date 30 days from date of publication of notice in the FEDERAL REGISTER] will be considered, in addition to the current non-exclusive applications under consideration, for the prospective license territory and field of use to be granted under the contemplated exclusive patent license.

ADDRESSES: Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Whitney A. Hastings, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 451-7337; Facsimile: (301) 402-0220; E-mail: hastingw@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This technology is based on the discovery of differentially expressed thyroid (DET) genes and their encoded proteins whose expression levels can be correlated to benign or malignant states in a thyroid cell.

Specifically, this data arose from a microarray analysis of genes expressed in the eight subtypes of thyroid tumors that are typically difficult to diagnose by cytology of fine needle aspiration (FNA) biopsies. Analysis of the (DET) genes led to the development of 6 gene and 10 gene models that distinguish benign vs. malignant papillary thyroid tumors. Subsequently, a 72 gene model has been developed for diagnosing less common forms of thyroid cancer such as follicular carcinoma. These results provide a molecular classification system for thyroid tumors and this in turn provides a more accurate diagnostic tool for the clinician managing patients with suspicious thyroid lesions. In addition to diagnostics, this invention can be used in the staging of thyroid malignancies by measuring changes in DET gene and protein expression relative to reference cells. Finally, this invention can also be used in the discovery of therapeutic agents through the detection in changes of DET gene and protein levels prior to and after treatment.

The prospective exclusive license and any further license applications received as objections to this Notice of Intent to Grant an Exclusive License, will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within thirty (30) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Any additional applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public

inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

July 13, 2012
Date

Richard U. Rodriguez, M.B.A.
Director
Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

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